ESRD Outpatient Medications Project

Network 8, Inc.

and

The University of Mississippi School of Pharmacy

Background

- The Part D benefit is a one-size fits all benefit that *could* disadvantage certain populations
- CMS wanted to ensure that the needs and care of the ESRD population was not adversely affected by this benefit
- CMS also has a need to start thinking about quality and performance

Purpose of the Project

- To establish a baseline of medication use by ESRD dually-enrolled patients
- To identify instances of inappropriate medication use that warrant further review
- To assist in the implementation of the Medicare Modernization Act (MMA) Part D prescription program

Methods

- Review of Literature
- Analysis of Medication Utilization
  - Data analysis of dually-enrolled ESRD and non-ESRD beneficiaries
    - Demographics
    - Medication prevalence
  - Initial data limited to MS (limits) and AL (no limits) patients—pending national sample
- Review of information and identification of medication issues by technical expert panel (TEP)

Technical Expert Panel

- 12 member panel composed of six MDs, three Pharm.D.s—a transplant recipient/PharmD, and two industry representatives.
- "to assist. . .in determining ESRD specific drug classifications and identifying drugs not recommended for ESRD patients"
- "will assist. . .by proposing criteria which can be used for future development of an ESRD-specific drug utilization review protocol."

Initial Meeting

- First TEP meeting November 17, 2004.
  - Review literature
  - Comment on the creation of ESRD-specific drug classes, using disease states:

    For example:

    Hyperlipidemia Bone disease

    Hypertension Anemia
  - Comment on a preliminary list of drugs not recommended for ESRD patients

Community Input

- Created "input document" for Renal Community based on initial TEP comments
- USP model guidelines released as "input document" was about to be circulated
- In consultation with CMS, "input document" revised and disseminated to the community on March 10

Second TEP

- Second TEP meeting April 13, 2005
  - Review comments from Renal Community
  - Review queries run by UM: drug-drug, drug-disease, prevalence of use of drugs identified at first TEP
  - Based on analyses of medication prevalence within existing classifications, finalize comments on ESRD-specific drug classes

Second TEP

- Using the USP Guidelines – Provided comments regarding
  - Drugs not appropriate for ESRD patients (AVOID)
  - Drugs that need to always be available (ALWAYS AVAILABLE)
  - Drug classification scheme in light of ESRD patients' needs

Current Status

- Based on
  - Background information
  - Description of medication use
  - TEP
  - Community input
- Medication Issues
- Classification Scheme

Drugs to Avoid (over 23)

- Meperidine
- Ketorolac (Avoid oral)
- Clavulanate
- Oxytetracycline
- Tetracycline
- Demeclocycline
- Nitrofurantoin
- Methenamine
- Probenecid
- Ribavirin (Oral)
- Metformin (and any metformin combination product)

Drugs to Avoid (over 23)

- Trizivir (Use single agent Abacavir, Lamivudine and Zidovudine)
- Combivir (Use single agent Lamivudine and Zidovudine)
- Truveda
- Epzicom
- Dofetilide
- Immediate release nifedipine
- Acetazolamide
- Fenofibrate
- Acamprosate (Campral)
- Aluminum with Citrate
- Low Molecular Weight Heparins (unless use is at adjusted doses with Factor Xa monitoring)
- Thiazide diuretics – as a sole diuretic

Always Available

- Based on TEP comments, over 80 medications must always be available to ESRD patients
- Commented on reclassifications of certain medications
  - Calcium Acetate – Current USP categorizes as Therapeutic Nutrients/Minerals/Electrolytes
  - Calcium Acetate
    - Gastrointestinal Agents: calcium-containing phosphate binders

Other Comments

- Drug Utilization Review

  For example:
  - Early refills with phosphate binders, like calcium acetate are a regular occurrence
  - In some instances, greater than usual doses are used

Final Report

- Report to CMS will:
  - Provide background on the treatment of ESRD
  - Discuss inappropriate medication use
  - Serve as baseline that can be used for determining the impact of medication errors and identification of methods to prevent such
  - Propose medication-related considerations
  - Propose further areas of medication-related investigation

Questions or comments?